

What Every Compliance Officer Needs to Know About Research... But is Afraid to Ask

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Agenda

- What is research?
 - Important Definitions
 - Participants
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- The Common Rule: Protecting Human Subjects
 - The IRB
 - Informed Consent
- Other Federal Rules: Conflicts of Interest
 - The Public Health Service
 - The Food and Drug Administration
- Dealing with Adverse Events
- Billing Issues
 - Fraud and Abuse
 - Medicare Secondary Payer Rules
 - CMS Clinical Research Policy
- Dealing with Research Misconduct



What is Research? It Depends...

- According to the Common Rule, *research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. 45 C.F.R. § 46.102(d).
- According to Public Health Service ("PHS") regulations, *research* is a systemic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied. 42 C.F.R. § 93.222.



Participants in Research

- Government Agencies
 - May regulate or even sponsor research studies.
- Sponsors
 - Entities that pay for and facilitate research studies, including the federal government, pharmaceutical companies, medical device companies, charitable foundations, universities and private individuals.
- Institutions
 - Entities in which research is conducted, including academic medical centers, hospitals, physician groups, and contract research organizations.
- Investigators
 - Persons who plan, carry out, and publish the results of research studies. The lead investigator may be referred to as the “Principal Investigator” or “PI.”
- Institutional Review Boards
 - Entities that evaluate research studies to ensure the safety of human subjects.

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Agencies Involved in Regulating Research

- The Department of Health and Human Services (“DHHS”) has been the most active agency in protecting human research subjects.
 - DHHS and several of its component agencies, including the Food and Drug Administration (“FDA”) and the Public Health Service (“PHS”) have promulgated regulations regarding the protection of human subjects.
 - DHHS component agencies, the Office of Research Integrity (“ORI”) and the Office of Human Research Protections (“OHRP”) also take an active role in regulating research activities.
- In addition to DHHS and FDA, 15 other agencies have endorsed the “Common Rule” regulating federally funded research to protect human subjects.
 - These include: Department of Agriculture, Department of Commerce, Department of Defense, Department of Education, Department of Energy, Department of Housing and Urban Development, Department of Justice, Department of Transportation, Department of Veterans Affairs, Agency for International Development, Consumer Product Safety Commission, Environmental Protection Agency, International Development Cooperation Agency, National Aeronautics and Space Administration, and National Science Foundation.

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The Common Rule Background

The Common Rule (45 C.F.R. Part 46) applies to all human subject research that is conducted, supported or subject to regulation by the 17 federal agencies that have adopted the Rule. This includes all research subject to FDA regulation and research that is funded by various DHHS agencies.

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The Common Rule Basic Requirements

- Written Assurance: Every institution that is involved in covered research activities must provide written assurance to the federal department or agency to which the institution must report.
- The “Assurance” is the institution’s formal commitment to protect human subjects in research.
- An institution need only file one “Federalwide” assurance, approved by the DHHS Office of Human Research Protections (“OHRP”), to cover all of its research activities.

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The Common Rule Assurance

The assurance must contain:

- A statement of principles to which the institution agrees to submit (OHRP has indicated that the Belmont Report is a suitable statement of principles for domestic institutions).
- Designation of an Institutional Review Board (“IRB”), for which the institution agrees to provide adequate resources.
- A list of IRB members, their expected contributions to the IRB and their relationship to the institution.
- A list of written procedures that the IRB will follow.
- Written procedures for ensuring prompt reporting to the IRB, institutional officials and the government agency regarding unanticipated problems, noncompliance with IRB directives and IRB suspensions or termination of research.

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IRBs: What they are and how they work

IRBs evaluate research studies in order to ensure the safety of human subjects. Each federally funded research study conducted within an institution must be reviewed and approved by an IRB before it is commenced.

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The Common Rule IRB - Membership

- IRB Membership:
 - At least 5 members with varying backgrounds
 - Sufficiently qualified through experience, expertise and diversity to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects
 - Includes at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas.
 - Includes at least one member who is not otherwise affiliated with the institution.
 - An IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote on the IRB.

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The Common Rule IRB – Approval of Research

- Criteria for IRB Approval of Research:
 - Risks to subjects are minimized;
 - Risks to subjects are reasonable in relation to anticipated benefits;
 - Selection of subjects is equitable;
 - Informed consent will be sought from each prospective subject;
 - When appropriate, the research plan makes provision for monitoring of research to ensure the safety of subjects; and
 - When appropriate there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.

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The Common Rule IRB – Termination of Research

An IRB shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, the institution and the government agency.

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The Common Rule IRB - Recordkeeping

- An IRB must maintain “adequate documentation” of its activities, including:
 - Copies of all research proposals and supporting documents reviewed;
 - Minutes of IRB meetings, in sufficient detail to show attendance, actions taken, the vote on actions taken, the basis for requiring changes to research or disapproval of research, and a written summary of the discussion of controverted issues and their resolution;
 - Records of continuing review activities;
 - Copies of correspondence between the IRB and investigators;
 - A detailed list of all IRB members;
 - Detailed written procedures; and
 - Statements of significant new findings provided to subjects.
- Records must be retained for at least 3 years after completion of the research.

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The Common Rule Informed Consent

No investigator may involve a human being as a subject in research covered by the Common Rule unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative.

The information that is given to the subject shall be in language understandable to the subject. *No informed consent may contain exculpatory language through which the subject must waive or appear to waive any of the subject’s legal rights.*

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The Common Rule Informed Consent

- Informed consent shall be documented by the use of a written consent form, approved by the IRB.
- In certain situations, the IRB may waive the requirement for a written consent form.

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The Common Rule Informed Consent

- Basic elements of informed consent:
 - A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed and identification of any procedures that are experimental;
 - A description of reasonably foreseeable risks and discomforts;
 - A description of reasonably foreseeable benefits;
 - A disclosure of appropriate alternative procedures or courses of treatment;
 - A statement describing the extent to which confidentiality of records will be maintained;
 - An explanation regarding whether any compensation or treatment will be offered if injury occurs;
 - An explanation regarding who to contact with questions; and
 - A statement that participation is voluntary.

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Public Health Service Regulations Overview

- The stated purpose of the PHS regulations is to promote objectivity in research – “to ensure there is no reasonable expectation that the design, conduct or reporting of research funded under PHS grants . . . Will be biased by any conflicting financial interest of an investigator.”
 - 42 C.F.R. Part 50, Subpart F

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PHS Regulation Requirements



- The institution must maintain a written and enforced policy regarding conflicts of interest.
- The institution must seek financial disclosure statements from investigators.
- Investigators must disclose significant financial interests.
- The institution must provide guidelines regarding conflicts of interest.
- The institution must keep records of financial disclosures.
- The institution must enforce its policy.

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PHS Regulations “Significant Financial Interests”

- A “Significant Financial Interest” means anything of monetary value subject to certain exceptions.
- Does not include:
 - Salary or royalties from the applicant institution.
 - Any ownership interest in the institution if it is an applicant under the Small Business Innovation Research Program.
 - Income from teaching, seminars or lectures sponsored by public or non-profit entities.
 - Income from service on advisory committees or review panels for public or non-profit entities.
 - An equity interest, which when aggregated with the investigator’s immediate family, does not exceed \$10,000 or represent more than 5% ownership in the entity.
 - Salary, royalties or other payments which, when aggregated with the investigator’s immediate family over the next twelve months, are not expected to exceed \$10,000.



PHS Regulations Managing Conflicts

- A designated official must review all financial disclosures and determine whether conflicts of interest exist. The regulations suggest that conflicts may be managed through:
 - Public disclosure
 - Monitoring research by independent reviewers
 - Modifying the research plan
 - Disqualifying the investigator from participating
 - Divesting the significant financial interest
 - Severing the relationships that create the conflicts



PHS Regulations Remedies to Lack of Compliance

- If an investigator refuses to comply with the PHS Regulations, the institution must:
 - Notify the PHS Awarding Component of the corrective action to be taken;
 - Comply with any instruction given by the PHS Awarding Component; and
 - After a finding of non-compliance by PHS, require that the investigator disclose the conflicting interest in each public presentation of the results of the research.



FDA Regulations Financial Conflicts of Interest

- The FDA Regulations regarding financial conflicts of interest apply to all entities that submit a marketing application for a new drug.
- Although financial disclosures are not made to the FDA until research is completed, the sponsor must prospectively apply these regulations to ensure that its later disclosure will meet the approval requirements for the marketing application.
- Applicable regulations provide that before permitting an investigator to begin participating in an investigation, the sponsor shall obtain sufficient accurate financial information to permit the sponsor to submit the disclosure statements required by 21 C.F.R. Part 54.


FDA Regulations Reporting Requirements

- Financial Interests that must be reported include:
 - Any compensation arrangement between the sponsor and the investigator that is dependant on or affected by the outcome of the trial.
 - Any significant payments having a cumulative monetary value of \$25,000 or more from the sponsor of the covered study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation or honoraria.
 - Any proprietary interest in the tested product held by any investigator involved in the study.
 - Any significant equity interest of \$50,000 or more that the investigator has in the sponsor.
 - Any steps taken to minimize the potential for bias resulting from the disclosed arrangements, interests or payments.

Managing Adverse Events

- Adverse events may implicate many regulatory requirements. A research institution should have in place a systematic approach to investigating, managing and promptly reporting the findings on adverse events. Such a systematic approach may include the following considerations:
 - Investigation: An immediate investigation should take place to determine the cause of the adverse event.
 - Sequestration: As part of the investigation, all pertinent documentation, ancillary record information and equipment or devices should be sequestered pending the disposition of the matter.
 - Interviews: Information should be obtained from first-hand observers and well documented.






Managing Adverse Events

- Communication regarding the Adverse Event:
 - Determine whether the event requires reporting.
 - Federal law/regulations may require reporting.
 - Contractual obligations with a private sponsor may require reporting.
 - Determine who should receive a report.
 - Government Agency?
 - Liability Insurer?
 - IRB?
 - State Medical Board?
 - DHHS Office of Research Integrity?
 - Disclosing information to research participants.
 - Participants may want to know:
 - Will I recover? How long will it take?
 - Does this mean I am out of the study?
 - Who pays for my injury-related care?
 - To whom can I complain?






Managing Adverse Events

- Under the Common Rule, the Institution's Assurance document must contain written procedures for ensuring prompt reporting to the IRB, institutional officials and the government agency regulating the research regarding :
 - Any unanticipated problems involving risks to subjects or others; and
 - Any suspension or termination of IRB approval.

Billing Issues Overview

- The False Claims Act
- Anti-Kickback Statute
- Stark Law
- Medicare Secondary Payer Rules
- CMS Clinical Research Policy
- Risks of Non-Compliance

The False Claims Act

- The Civil False Claims Act (31 U.S.C. § 3729 et seq.)
 - The federal government, state attorney general or a private party may sue any person or entity whom it believes has knowingly presented a false or fraudulent request for payment to the government, or who has made a false statement or used a false record in support of such a claim.
 - Specific intent is not necessary, but simple mistake is not enough.
 - Penalties include fines of \$5,500 to \$11,000 per false claim, plus treble damages.
- Medicare and Medicaid False Claims Act Provisions (42 U.S.C. § 1320a-7b(a))
 - It is a federal felony if a person knowingly and willfully makes or causes to be made any false statement or representation of material fact in any claim or application for benefits under a federal health care program (including Medicare and Medicaid).
 - Forms the basis for the obligation to refund “overpayments” of Medicare or Medicaid receipts.
 - Punishment includes up to 5 years imprisonment, \$25,000 in fines and program exclusion.

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The Anti-Kickback Statute

- The Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))
 - Nothing of value (remuneration in cash or “in kind”) may be offered or received, directly or indirectly, to induce or provide the referral of patients or business, the purchase, lease, order or arranging for the purchase, lease or order of any good, facility, service or item, for which payment may be made in whole or in part under a federal health care program.
- Penalties:
 - Felony with up to five years imprisonment and/or \$25,000 fine;
 - Exclusion from participation in federal health care programs, including Medicare and Medicaid; and
 - Possible loss of state licensure, hospital privileges, and managed care participation.
- Statutory Exceptions:
 - Payments to bona fide employees.
 - Certain discounts.
 - Payments to a purchasing agent.
 - Regulatory safe harbors.
 - Specified risk-sharing arrangements.

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Stark Law

- The Stark Law (42 U.S.C. § 1395nn)
 - Prohibits the referral of patients by physicians with financial relationship with entities that furnish certain designated health services (“DHS”). If a physician has a financial relationship with an entity, that physician may not make a referral to that entity for the provision of DHS for which payment may be made under the Medicare or Medicaid programs.
 - The Stark Law is a strict liability statute.
 - Penalties include the denial of payment, mandatory refund of any payments previously received, civil monetary penalties of up to \$15,000 per referral, and exclusion from the Medicare and Medicaid programs.
- Exceptions:
 - There are three types of exceptions set forth in the statute: those applicable to both ownership and compensation arrangements, those that protect only ownership interests and those that protect only compensation arrangements.
 - The Stark Law also gives DHHS the authority to adopt additional regulatory exceptions under certain circumstances.
- Regulations:
 - Stark regulatory exceptions have been frequently changed and the current regulations should be consulted regarding new transactions. 42 C.F.R. § 411.350 et seq.

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FCA Interpretation
U.S. ex rel. Cantekin v. University of Pittsburgh

- Allegation:
 - A medical researcher failed to disclose information about sources of research funding on NIH grant applications, implicating the FCA.
- Outcome:
 - The 3rd Circuit Court of Appeals found that because the PI knowingly omitted to include several million dollars in alternative funding from pharmaceutical companies on his NIH grant applications, the grant applications constituted false claims.
 - The Court did not determine whether the FCA included a materiality requirement, but decided that the omission was nevertheless material.
 - "... industry funding is relevant for assessing conflicts of interest, how much time an applicant has to devote to the requested NIH grant, and how the research fits within a broader research program . . . a reasonable NIH grant applicant would know that the NIH regards the information as important."
 - The NIH specifically requested the alternative funding information on the grant application form.
 - 192 F.3d 402 (3d Cir. 1999).

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FCA Interpretation
U.S. ex rel. Villafane v. Sollinger

- Allegation:
 - The financial arrangement between the hospital, university research foundation, physicians and others violated the Stark Law and Anti-Kickback Statute and was therefore actionable under the FCA.
- Outcome:
 - The District Court dismissed the FCA allegations because it found the arrangement to fit within the Stark Academic Medical Center exception.
 - Physicians were faculty members.
 - Compensation was reasonable, unrelated to referrals and sufficiently documented.
 - There was no evidence of illegal kick-backs.
 - The Court specifically stated, however, that violations of the Stark Law and Anti-Kickback Statute can be used to support an FCA action.
 - 457 F. Supp. 2d 743 (W.D. Ky. 2008).

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Medicare Secondary Payer Rules

- The Medicare Secondary Payer Rules require providers to identify all other payers, such as commercial insurers, before billing Medicare for services. Medicare regulations at 42 C.F.R. § 411.32 state "Medicare benefits are secondary to benefits payable by a primary payer even if State law or the primary payer states that its benefits are secondary to Medicare benefits or otherwise limits its payments to Medicare beneficiaries."
- CMS interpreted its policy in an April 2004 letter, indicating that a statement by a trial sponsor that it would "pay for medically necessary services" to treat injuries related to the clinical trial if the patient's insurance would not cover those costs is considered "insurance" for primary payment responsibility.
- This means that if the sponsor guarantees payment for injury-related patient care, Medicare, not the sponsor, is the payer of last resort.
- Consistent with Congressional intent?

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CMS Clinical Research Policy

- **National Coverage Determinations Manual § 310.1 - Routine Costs in Clinical Trials:** Effective for items and services furnished on or after July 9, 2007, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.
- Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:
 - The investigational item or service, itself unless otherwise covered outside of the clinical trial;
 - Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
 - Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

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CMS Clinical Research Policy

- Medicare MLN Matters Article SE0822 (Sept. 2008)
 - 1. Question: If a research sponsor says in writing that they will pay for routine costs if there is no reimbursement from any insurance company (including Medicare), does that fall into the "free of charge" category.
 - Answer: If the routine costs of the clinical trial are furnished gratuitously (i.e. without regard to the beneficiary's ability to pay and without expectation of payment from any other source), then Medicare payment cannot be made and the beneficiary cannot be charged. If private insurers deny the routine costs and the provider of services does not pursue the non-Medicare patients for payment after the denials (even though the non-Medicare patient has the ability to pay), Medicare payment cannot be made and the beneficiary cannot be charged for the routine costs.

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CMS Clinical Research Policy

- Chapter 16, section 40 of the Medicare Benefit Policy Manual outlines the policies regarding payment of routine costs of clinical trials, and states:
 - "Program payment may not be made for items or services which neither the beneficiary **nor any other person or organization** has a legal obligation to pay for or provide."
- If a sponsor is obligated to and actually does pay for something in a clinical trial, then somebody - the sponsor - has an obligation to pay.
- The payment policy is inconsistent with the MLN Matters Article.
- On January 7, 2009 CMS revised and reissued MLN Matters Article SE0822 to delete "Question 1" referred to on the previous slide.

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Billing Issues Risks of Non-Compliance

- Institutions:
 - Damage to institution's reputation in scientific community;
 - Possible loss of funding;
 - Risk of fines and penalties;
 - Settlement costs (including legal expenses) and/or damages arising from FCA actions; and
 - Possible termination of research activities.
- Individuals:
 - Loss of Principal Investigator status;
 - Debarment, suspension and exclusion; and
 - Criminal and/or civil sanctions.

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Research Misconduct

- Research Misconduct is fabrication, falsification or plagiarism in proposing, performing or reviewing research or in reporting research results.
 - Fabrication is making up data or results and recording or reporting them.
 - Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
 - Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

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Research Misconduct



- PHS awardees and applicant institutions are required to address and report possible research misconduct.
 - PHS Includes: National Institutes for Health (NIH), The Centers for Disease Control and Prevention (CDC), The Food and Drug Administration (FDA), The Substance Abuse and Mental Health Services Administration (SAMHSA), The Health Resources and Services Administration (HRSA), The Agency for Healthcare Research and Quality (AHRQ), The Agency for Toxic Substances and Disease Registry (ATSDR), and The Indian Health Service (IHS).
 - 42 C.F.R. Part 93
 - Other Agencies may have similar misconduct policies, including the National Science Foundation, the Department of Labor, the Department of Transportation, the Veterans Administration, the Environmental Protection Agency, NASA and the Department of Energy.

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Research Misconduct What to do...the Allegation

- Allegation of research misconduct is made
 - *Is the allegation credible and specific?*
 - *Does it meet the definition of research misconduct?*
 - *Does it involve PHS funded research?*
 - *If yes to all of the above, proceed to the Inquiry.*



Research Misconduct What to do...the Inquiry

- **Inquiry:** Information gathering and initial fact finding to determine whether an allegation or apparent instance of misconduct warrants an investigation.
 - *Must be completed (including the report) within 60 days, unless circumstances clearly warrant a longer period.*
 - *At or before beginning inquiry, an institution must make a good faith effort to notify the presumed Respondent in writing of the initiation of the proceeding.*
 - *The Institution's Inquiry Panel/Committee conducts the proceeding.*
 - **Sequestration of Research Records**
 - Seize all research records and evidence including notebooks, print outs, data, case report forms, animals, cell lines, computer files, progress reports, journals, etc.
 - Inventory the records and evidence.
 - Sequester in secure manner.
 - *If an Inquiry results in an Investigation, the institution must notify the Office of Research Integrity (ORI) within 30 days.*
 - Provide the ORI with the Inquiry report.
 - Provide the Respondent with written notice.
 - *If the Inquiry does not result in an Investigation, no notice is required to the ORI.*
 - Must keep documents for 7 years after the termination of the Inquiry.
 - Doesn't include "settlements" which are reportable to the ORI.
 - Provide the Respondent with written notice.

Research Misconduct What to do...the Investigation

- **Investigation:** Formal development and evaluation of a factual record in order to determine, whether, based on a preponderance of the evidence, research misconduct occurred, and if so to what extent, who was responsible and how serious was it.
 - **Timing:**
 - Begin within 30 days of completion of the Inquiry.
 - Complete within 120 days, including the Investigative Report.
 - **Notice to Respondent:**
 - Make notice within a "reasonable amount of time" after the Inquiry, but before the Investigation begins.
 - Provide a draft of the Investigative Report to the Respondent for comment. Comments must be considered if received within 30 days.
 - Institution may provide Respondent with supervised access to the evidence.

Research Misconduct What to do...the Investigation

- The Investigation:
 - Conducted by an Investigation Panel/Committee.
 - Examine all documentation and evidence.
 - Interview Respondent, Complainant and other witnesses.
 - Record or transcribe interviews.
 - Provide recordings or transcriptions to interviewees for corrections.
- Notice to ORI includes:
 - The Report
 - Findings
 - Final Institutional Actions
- Records must be retained for 7 years.

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